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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,179	07/11/2003	Bernard F. Erlanger	64081/JPW/AJM/MVM	4371

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EXAMINER	
WANG, LOUISE Z	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,179	ERLANGER ET AL.	
	Examiner	Art Unit	
	Louise Wang	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted that Claim 20 depends on Claim 18 and recites "the antibody and second moiety" for which there is insufficient antecedent basis. For restriction purposes, Claim 20 is presumed to depend on Claim 19.

It is also noted that Claim 22 uses improper Markush language.

Correction is required.

Sequence Compliance

The specification and claims are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. See the HIV Tat peptide sequence in Claim 12. See 37 CFR §1.821(d). Full compliance is required in response to this Restriction Requirement. A reply that fails to comply will be considered to be non-responsive and may result in abandonment of this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 37, and 38, drawn to a composition comprising an antibody and a peptide moiety, and a kit comprising the composition, classified in class 435, subclass 810.

II. Claims 1-22, 39, and 40, drawn to a composition comprising an antibody and a peptide moiety, wherein the antibody is bound to a second agent, and a kit comprising the composition and reagents for affixing the second agent to the composition, classified in class 435, subclass 810.

III. Claim 23, drawn to a method for making the composition of an antibody and a peptide moiety, classified in class 530, subclass 402.

IV. Claims 24 and 25, drawn to a method for introducing an antibody into a cell, classified in class 435, subclass 449.

V. Claims 26 and 27, drawn to a method for determining whether an agent is present in a cell comprising contacting the cell with an antibody labeled with a detectable marker and a peptide, classified in Class 424, subclass 9.1.

VI. Claims 28 and 29, drawn to a method for introducing an agent into a cell comprising affixing the agent to an antibody and contacting the cell with a composition of the antibody and a peptide, classified in class 435, subclass 440.

VII. Claims 30, 32-36, drawn to a method for treating a human disorder comprising administering the composition of an antibody that targets an intracellular agent, and a peptide, classified in class 424, subclass 133.1.

VIII. Claims 31, 32-26, drawn to a method for treating a human disorder comprising administering the composition of an antibody bound to a secondary therapeutic agent, and a peptide, classified in class 424, subclass 133.1.

Inventions I and II are distinct from each other because of their structures and/or modes of action. An antibody-peptide composition bound to a second agent has different biological and physicochemical properties than the antibody-peptide composition by itself. Binding a second agent can alter its structure, binding specificity, mode of action, and function, thus each invention represents a patentably distinct subject matter.

Inventions III-VIII are different methods with respect to starting materials, physiological mechanisms, protocol procedures, and end products; therefore, each method is patentably distinct.

Inventions I and III are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition can be made by an amino acid synthesizer or by transformation of a cell with a vector co-expressing the antibody and the peptide moiety and subsequent co-purification of the antibody and peptide. The process as claimed can be used to make pharmaceutical drug compounds or diagnostic reagents.

Inventions (I and II) and (IV-VIII) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the processes for using the antibody-peptide composition with or without a secondary agent, as claimed, can be practiced with other

materials: a hybridization probe, an aptamer, or PCR primers can be used to determine whether an agent is present in a cell; a virus vector, a lipid peptide or a liposome can be used to introduce an agent into a cell; a different drug compound can be used to treat human disorders. The products as claimed can be used in affinity purification of antigens, in addition to the methods of therapeutic treatment, drug delivery, and detection as recited.

These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Furthermore, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I or II is elected, Applicant is required to elect a specific peptide from the following:

(a) poly-L-lysine

(b) poly-L-arginine

(c) poly-L-ornithine; or

(d) SEQ ID NO: 1.

These protein species are distinct because their amino acid sequences, structures, and/or modes of action are different; thus, each peptide represents patentably distinct subject matter. Furthermore, the examination of these species would require different searches in the scientific literature, which would not be coextensive. As such, it would be burdensome to search these Species together.

If Group II or VI is elected, Applicant is further required to elect a specific second agent from the following:

(a) a detectable marker;

(b) a probe;

(c) a small molecule;

(d) a peptide;

(e) an antibody; or

(f) a nucleic acid.

If Applicant elects the first species from above, i.e. a detectable marker, then Applicant is also required to elect a specific detectable marker as well, from the following:

(i) a radioactive label;

(ii) a colorimetric marker;

(iii) a luminescent marker; or

(iv) a fluorescent marker.

If Group IV is elected, Applicant is required to elect a specific antigen from the following:

(1) a reactant;

(2) a product; or

(3) a catalyst.

These species are distinct because their structures, physicochemical properties and modes of action are different. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

If Group VII is elected, Applicant is required to elect a human disorder from the following:

(1) toxication;

(2) cancer; or

(3) HIV infection.

These species are distinct because their etiologies are different and require different mechanisms of inhibition. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 3, 4, 21, 22, 25, and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Louise Wang
Patent Examiner
June 24, 2005

JEFFREY STUCKER
PRIMARY EXAMINER